

REMARKS

Reconsideration of the above-identified application in view of the preceding amendments and the following remarks is respectfully requested.

Claims 1-20 are presently pending in this application. Claims 1, 10 and 17-20 have been amended to more particularly point out and define subject matter regarded as inventive. No new matter has been added to the subject application by these amendments nor have any new issues been raised. Support for these amendments is found throughout the written specification and drawings of the subject application.

DETAILED ACTION

The Specification

The disclosure was objected to because of certain informalities. Appropriate corrections have been made to the specification.

Claim Objections

Claims 18-20 were objected to because of certain informalities. Appropriate corrections have been made to the claims.

Rejection Under 35 U.S.C. §102(b)

Claims 1-3, 5, 10 and 12 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,242,431 to Kristiansen.

Kristiansen disclose a suture sleeve assembly 10 for gripping a lead body 12. The assembly 10 includes a tubular body 14 having a longitudinal axis 16 and a through bore 18 for receiving the lead body. A slidable collar 50 is operatively associated with the tubular member 14. The tubular body 14 has three portions, including a first portion 20, a second portion 22 and

a third portion 24. "The first portion 20 of tubular body 14 has a generally cylindrical, concentric inner and outer surfaces 26 and 28 respectively. Similarly, the second portion 22 of tubular body portion 14 has a generally cylindrical outer surface 30 and a generally cylindrical inner surface 32 concentric with the outer surface." (Col. 3, lns. 45-50). The third portion of the tubular body 14 is located between the first and second portions, and it has an outer surface 34 that tapers outwardly. (see Col. 3, lns. 60-64). Thus, Kristiansen does not disclose a device having an elongated body with an open interior channel extending substantially along its length.

In contrast, Claim 1 as amended, defines a device for delivering implantable cardiac leads to an implantation site that includes, among other things, an elongated carrier body having an interior channel that is open along substantially the entire length of the carrier body for accommodating a cardiac lead, and means mounted for movement along the length of the carrier body for releasably securing the cardiac lead within the open interior channel of the carrier body during delivery to an implantation site. Kristiansen does not disclose or suggest a lead delivery device with an open channel extending substantially along its length. Rather, Kristiansen discloses a tubular body that is closed along its entire length.

Similarly, Claim 10, as amended, recites a device for delivering implantable cardiac leads to an implantation site that includes, among other things, an elongated carrier body having an open interior channel with a generally U-shaped cross-section for accommodating a cardiac lead, and an adjustable collar mounted for movement along the carrier body for releasably securing the lead within the open interior channel of the carrier body during delivery to an implantation site. Kristensen does not disclose or suggest a lead delivery device having an open generally U-

shaped channel. Rather, Kristansen disclose a tubular body having a circular cross-section of varying diameter along its length.

In sum, Claims 1 and 10 and each of the claims depending respectively therefrom are not anticipated by U.S. Patent No. 5,242,431 to Kristiansen, and withdrawal of the rejection under 35 U.S.C. §102(b) based upon the '431 patent is respectfully requested.

Claims 1, 17 and 18 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,972,847 to Dutcher et al.

Dutcher et al. ('847) disclose a tool for implanting a lead that includes a two-part cylindrical body 20 having interconnected flexible beam portions 37 and 38 that are biased apart from one another and pivotably connected at axially opposed pivots 47 and 48. A centrally located releasable lock assembly 82 locks the beams 37 and 38 together. Beam 37 has a longitudinal groove 39 on one side of body 20 and a longitudinal lip 41 partially closes groove 39 to retain a conductor 23 in the groove. Another groove 43 is formed in beam 38, which has a retaining lip 44. (see Fig. 5). Thus, Dutcher et al. ('847) do not disclose a device having an elongated body with an open interior channel extending substantially along its length or an adjustable collar movable along the length of the body to releasably retain a lead in the channel.

In contrast, Claim 1 as amended, defines a device for delivering implantable cardiac leads to an implantation site that includes, among other things, an elongated carrier body having an interior channel open along substantially the entire length of the carrier body for accommodating a cardiac lead, and means mounted for movement along the length of the carrier body for releasably securing the cardiac lead within the open interior channel of the carrier body during delivery to an implantation site. Dutcher et al. do not disclose or suggest a lead delivery device

with an open channel extending substantially along its length and means mounted for movement along the length of the carrier body for releasably securing the cardiac lead within the open interior channel of the carrier body. Rather, Dutcher et al. ('847) disclose a tool having a groove with a lip that partially closes the groove to retain a lead therein.

Similarly, Claim 17, as amended, defines a method for delivering implantable cardiac leads to a lead implantation site that includes, among others, the steps of providing a lead delivery device having an elongated carrier body defining an interior channel open along substantially the entire length of the carrier body for accommodating at least one implantable cardiac lead, and releasably securing the at least one implantable cardiac lead within the open interior channel of the carrier body with a movable collar. Dutcher et al. do not disclose or suggest such a method of lead implantation.

In sum, Claims 1 and 17 and each of the claims depending respectively therefrom are not anticipated by U.S. Patent No. 4,972,847 to Dutcher et al., and withdrawal of the rejection under 35 U.S.C. §102(b) based upon the '847 patent is respectfully requested.

Rejection Under 35 U.S.C. §103(a)

Claims 2, 3, 10, 19 and 20 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,242,431 to Kristiansen.

Neither Dutcher et al. ('847) nor Kristiansen disclose or suggest, either alone or in combination, in whole or in part a device, or a method providing a device, for delivering implantable cardiac leads to an implantation site that includes, among other things, an elongated carrier body having an open interior channel having a generally U-shaped cross-section for accommodating a cardiac lead, and means in the form of an adjustable collar mounted for

movement along the carrier body for releasably securing the lead within the channel of the carrier body during delivery to an implantation site. Moreover, a person of ordinary skill in the art would not have been motivated to combine these references, because there would be no reason to provide a movable collar on the implantation tool disclosed by Dutcher et al. as, since the tool already has a releasable locking mechanism associated therewith. Furthermore, such a collar would actually prevent the Dutcher et al. tool from operating in an intended manner, since the collar would prevent the beams of the tool from opening. Accordingly, Claims 2, 3, 10, 19 and 20 are not rendered obvious by the combination of references cited by the Examiner.

Claim 4 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 4,644,957 to Ricciardelli et al.

The deficiencies of Dutcher et al. ('847) are described above with respect to Claim 1. Ricciardelli et al. fails to overcome the deficiencies of Dutcher et al. ('847), including the failure to provide a movable means (e.g., a movable collar) for releasably securing a lead in a channel. Accordingly, Claim 4 is not rendered obvious by the combination of Dutcher et al. ('847) and Ricciardelli et al., at least for the reasons set forth above with respect to Claim 1.

Claim 5 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 4,209,019 to Dutcher et al.

The deficiencies of Dutcher et al. ('847) are described above with respect to Claim 1. Dutcher et al. ('019) fails to overcome the deficiencies of Dutcher et al. ('847), including the failure to provide a movable collar for releasably securing a lead in a channel. Accordingly, Claim 5 is not rendered obvious by the combination of Dutcher et al. ('847) and Dutcher et al. ('019), at least for the reasons set forth above with respect to Claim 1.

Claim 6 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 4,209,019 to Dutcher et al. and further in view of U.S. Patent No. 6,551,269 to Clemens et al.

The deficiencies of Dutcher et al. ('847) and Dutcher et al. ('019) are discussed above with respect to Claim 5. Clemens et al. fails to overcome the deficiencies of Dutcher et al. '847 and '019. Accordingly, Claim 6 is not rendered obvious by the combination of references cited by the Examiner, at least for the reasons set forth above with respect to Claim 1.

Claims 7-9 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,500,012 to Brucker et al.

The deficiencies of Dutcher et al. ('847) are described above with respect to Claim 1. Brucker et al. fails to overcome the noted deficiencies of Dutcher et al. ('847), including the failure to provide a movable collar for releasably securing a lead in a channel. Accordingly, Claims 7-9 are not rendered obvious by the combination of references cited by the Examiner, at least for the reasons set forth above with respect to Claim 1.

Claim 11 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,242,431 to Kristiansen and further in view of U.S. Patent No. 4,644,957 to Ricciardelli et al.

The deficiencies of Dutcher et al. ('847) and Kristiansen are discussed above with respect to Claim 10, as well as the notion that a person of ordinary skill in the art would not have been motivated to make the proposed combination. Ricciardelli et al. fails to overcome the noted deficiencies of Dutcher et al. ('847) and Kristiansen, alone and in combination, or provide any motivation for the combination. Accordingly, Claim 11 is not rendered obvious by the

combination of references cited by the Examiner at least for the reasons set forth above with respect to Claim 10.

Claim 12 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,242,431 to Kristiansen and further in view of U.S. Patent No. 4,209,019 to Dutcher et al.

The deficiencies of Dutcher et al. ('847) and Kristiansen are discussed above with respect to Claim 10, both alone and in combination. Dutcher et al. '019 fails to overcome the noted deficiencies of Dutcher et al. ('847) and Kristiansen, or provide any motivation for the combination.. Accordingly, Claim 12 is not rendered obvious by the combination of references cited by the Examiner at least for the reasons set forth above with respect to Claim 10.

Claim 13 was rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,242,431 to Kristiansen and U.S. Patent No. 4,209,019 to Dutcher et al. and further in view of U.S. Patent No. 6,551,269 to Clemens et al.

The deficiencies of Dutcher et al. ('847) and Kristiansen are discussed above, both alone and in combination. Both Dutcher et al. '019 and Clemens et al. fail to overcome the noted deficiencies of Dutcher et al. ('847) and Kristiansen, or provide any motivation for the proposed combination. Accordingly, Claim 13 is not rendered obvious by the combination of references cited by the Examiner at least for the reasons set forth above with respect to Claim 10.

Claims 14-16 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 4,972,847 to Dutcher et al. in view of U.S. Patent No. 5,242,431 to Kristiansen and further in view of U.S. Patent No. 5,500,012 to Brucker et al.

The deficiencies of Dutcher et al. ('847) and Kristiansen are discussed above with respect to Claim 10, both alone and in combination. Brucker et al. fails to overcome the noted deficiencies of Dutcher et al. ('847) and Kristiansen or provide any motivation to make the proposed combination. Accordingly, Claims 14-16 are not rendered obvious by the combination of references cited by the Examiner at least for the reasons set forth above with respect to Claim 10.

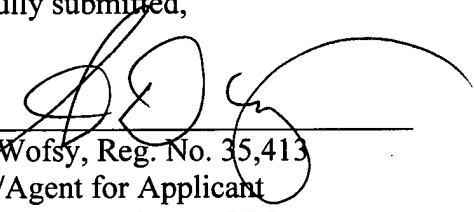
CONCLUSION

It is respectfully submitted that all of the claims presently under consideration in this application are directed to patentable subject matter, and allowance thereof is earnestly solicited.

If the Examiner believes that a telephonic or personal interview would resolve any remaining matters, the undersigned may be contacted at the telephone number provided below.

Respectfully submitted,

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